97CV550
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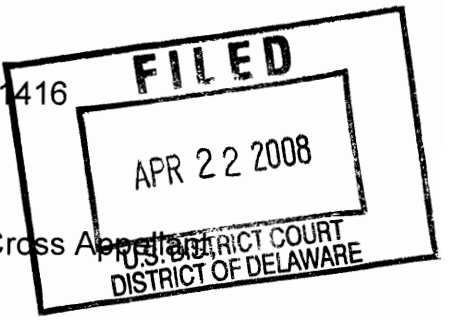
United States Court of Appeals for the Federal Circuit



2006-1393, -1394, -1395, -1396, -1415, -1416

CORDIS CORPORATION,

Plaintiff-Cross Appellant,

v.

MEDTRONIC AVE, INC.,

Defendant-Appellant,

and

BOSTON SCIENTIFIC CORPORATION
and BOSTON SCIENTIFIC SCIMED, INC. (formerly known as Scimed Life Systems, Inc.),

Defendants-Appellants.

MEDTRONIC AVE, INC.,

Plaintiff-Appellant,

v.

CORDIS CORPORATION, JOHNSON AND JOHNSON,
and EXPANDABLE GRAFTS PARTNERSHIP,

Defendants-Appellees.

BOSTON SCIENTIFIC CORPORATION
and BOSTON SCIENTIFIC SCIMED, INC. (formerly known as Scimed Life Systems, Inc.),

Plaintiffs-Appellants,

v.

ETHICON, INC., CORDIS CORPORATION,
and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO.,

Defendants-Cross Appellants.

Gregory L. Diskant, Patterson, Belknap, Webb & Tyler LLP, of New York, New York, argued for plaintiff-cross appellant/defendant-appellees/defendants-cross appellant Cordis Corporation, et al. With him on the brief were Eugene M. Gelernter, William F. Cavanaugh, Jr., Michael J. Timmons, Scott B. Howard, and Kathleen M. Crotty.

David M. Underhill, Boies, Schiller & Flexner LLP, of Washington, DC, argued for defendant-appellant/plaintiff-appellant Medtronic Ave, Inc. On the brief were William P. Atkins, George M. Sirilla, and Scott J. Pivnick, Pillsbury Winthrop Shaw Pittman LLP, of McLean, Virginia.

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Appealed from: United States District Court for the District of Delaware

Judge Sue L. Robinson

United States Court of Appeals for the Federal Circuit

2006-1393, -1394, -1395, -1396, -1415, -1416

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Defendants-Cross Appellants.

Appeals from the United States District Court for the District of Delaware in consolidated cases 97-CV-550, 97-CV-700, and 98-CV-19, Judge Sue L. Robinson.

DECIDED: January 7, 2008

Before BRYSON, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and, KEELEY, Chief District Judge.*

BRYSON, Circuit Judge.

These consolidated appeals arise from two related cases in the United States District Court for the District of Delaware. In both cases, Cordis Corp. alleged that the defendants had infringed its patents covering vascular stents that are used to treat coronary artery disease. After separate trials, Cordis obtained jury verdicts of infringement against defendant Medtronic AVE, Inc., ("AVE") in the first case and co-defendants Boston Scientific and Boston Scientific Scimed, Inc., (collectively, "BSC") in the second case. AVE and BSC each filed a motion for a new trial and for judgment as a matter of law ("JMOL"). They now appeal from the district court's denial of those motions. Cordis has cross-appealed from the district court's invalidation of a claim that the jury found to have been infringed by BSC. We affirm the judgments against AVE and BSC, and on Cordis's cross-appeal we reverse the invalidity ruling.

I

These appeals involve two patents, U.S. Patent No. 4,739,762 ("the '762 patent") and U.S. Patent No. 5,195,984 ("the '984 patent"). The '762 patent discloses a

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* Honorable Irene M. Keeley, Chief Judge, United States District Court for the Northern District of West Virginia, sitting by designation.

coronary stent that can be mounted on an angioplasty balloon and delivered to a target location intraluminally (i.e., through the vascular system) by a catheter. Once the stent and balloon reach the desired location, the balloon is inflated to expand the stent to a desired size. At issue in both cases is claim 23 of the '762 patent, which covers an expandable intraluminal vascular stent comprising "a . . . tubular member having . . . a wall surface . . . , the wall surface having a substantially uniform thickness and a plurality of slots formed therein." '762 patent, col. 11, ll. 63-67. Claim 23 further requires the wall surface to be a "smooth surface." Id., col. 12, ll. 57-58. The figures below, taken from the '762 patent, show the disclosed stent in its collapsed (Fig. 1A) and expanded (Fig. 1B) forms.

Fig. 1A

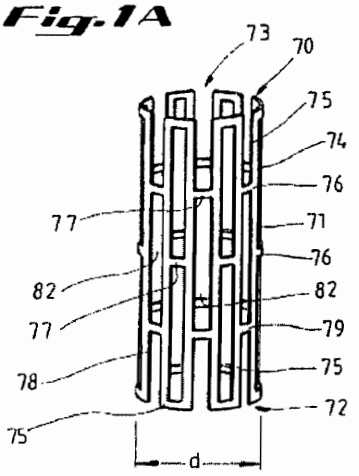
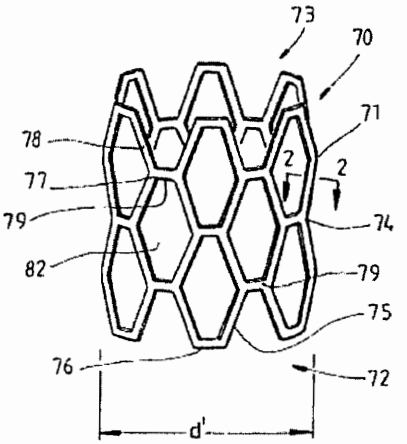


Fig. 1B



After the litigation against AVE and BSC was underway, Cordis requested reexamination of the '762 patent in light of a number of prior art references. During reexamination, Cordis narrowed the patent's scope by distinguishing the claimed invention from a prosthetic implant in the form of a tubular sleeve that is disclosed in U.S. Patent No. 3,657,744 to Ersek. Cordis amended its claims by canceling

independent claim 13 and incorporating all the limitations of that claim into claim 23, which had previously depended from claim 13. In remarks accompanying the amendment, Cordis distinguished the claimed invention from the Ersek sleeve based on the "wall surface," "smooth surface," and "substantially uniform thickness" limitations.

The second patent involved in these appeals, the '984 patent, discloses a flexible stent manufactured by joining tubular members, such as those disclosed in the '762 patent, by a connector that "provides the necessary flexibility to negotiate the bends and curves in tortuous body passageways, such as the vascular system." '984 patent, col. 4, ll. 23-25. The disclosed flexible stent is depicted in the figures below taken from the '984 patent.

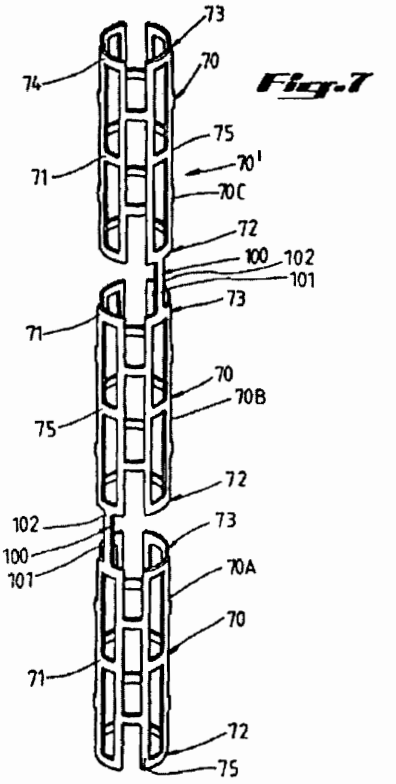


Fig. 7

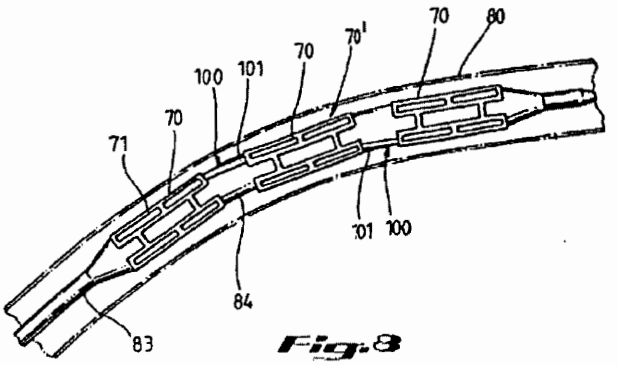
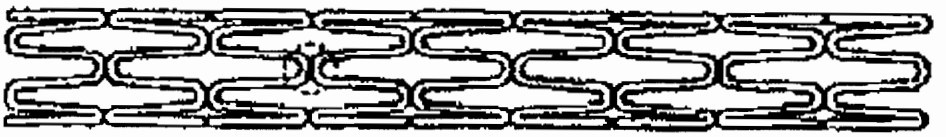


Fig. 8

II

We first address AVE's appeal. Cordis alleged that three of AVE's stents infringe the '762 and '984 patents: the MicroStent II, the GFX, and the GFX 2. Those stents are each made from rounded lengths of stainless steel that are formed into rings. The rings are heated to a temperature sufficient to permit them to be formed, and they are then folded into sinusoidal structures. Each sinusoidal ring has straight portions, which AVE refers to as "struts," and curved portions at the ends of the struts, which AVE refers to as "crowns." To create the complete stent, adjacent sinusoidal rings are welded together at a point between one of the crowns of each ring. The drawing below depicts one of the AVE stents consisting of multiple sinusoidal rings welded together; the dashed circle identifies one of the weld points between two crowns on adjacent rings.



The first trial in the AVE case was held in 2000. Prior to trial, the district court granted partial summary judgment for AVE, holding that its stents did not literally infringe the "plurality of slots formed therein" limitation. After trial, however, the jury returned a verdict in Cordis's favor, finding that AVE's stents infringed the '762 and '984 patents under the doctrine of equivalents. The district court then granted AVE's motion for JMOL of noninfringement under the doctrine of equivalents, holding that Cordis was barred from asserting equivalents for the "plurality of slots formed therein" and "substantially uniform thickness" limitations of claim 23. The district court also entered a conditional order granting a new trial on the issue of whether AVE's stents literally infringe the "substantially uniform thickness" limitation.

On Cordis's appeal, we reversed the district court's construction of the claim terms "plurality of slots formed therein" and "substantially uniform thickness." The district court had construed the "plurality of slots formed therein" to require that the slots be formed by removing material from a preexisting wall surface. We held that the slots were not required to be formed by any particular process. Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1356-60 (Fed. Cir. 2003) ("Cordis I"). We also held that the district court had erred in narrowly construing the "substantially uniform thickness" limitation. The district court had held that the prosecution history showed that in the course of distinguishing the Ersek sleeve, Cordis had disclaimed stents varying in thickness "by 0.001 inch or more." Id. at 1360. After reviewing the prosecution history, we concluded that Cordis had not clearly and unmistakably disclaimed stents having more than that degree of variation in thickness. Id. at 1362. Instead, we construed "substantially uniform thickness" to mean that "the walls must be of largely or approximately uniform thickness." Id. at 1360. We added that the prosecution history supported a finding that Cordis disclaimed stents having walls varying in thickness by at least 100 percent. Id. at 1362.

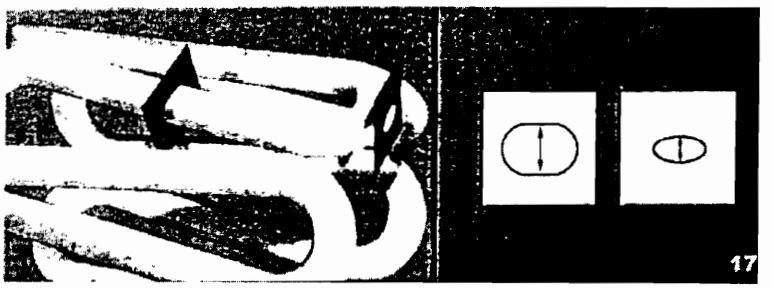
On remand, the district court in 2005 held a retrial on whether AVE's stents literally infringed the "substantially uniform thickness" limitation. The jury returned a verdict in Cordis's favor, and the district court denied AVE's motions for JMOL of noninfringement and a new trial. The district court also denied AVE's renewed motion for JMOL of noninfringement with regard to the '984 patent's "flexibly connect" limitation, which the jury in the 2000 trial had found infringed.

On appeal, AVE argues that it is entitled to JMOL of noninfringement of the '762 patent because its stents do not have walls with "substantially uniform thickness." It argues that it is entitled to JMOL of noninfringement of the '984 patent because the welds on its stents do not "flexibly connect" the individual sinusoidal rings. In the alternative, AVE argues that it is entitled to a new trial on several grounds.

A

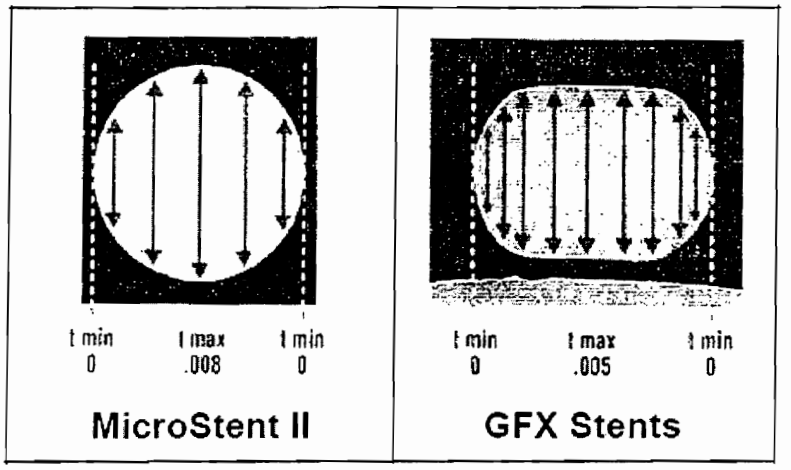
AVE first argues that its stents do not satisfy the "substantially uniform thickness" limitation of claim 23. AVE explains that its stents are made from a group of rings consisting of thin metal strands having circular or ellipto-rectangular cross-sections. Each ring is bent into a sinusoidal shape so that it forms a tube-like member. The tube-like segments are then welded together to form the stent. The sinusoidal segments therefore make up the wall of the stent. As a result of the sinusoidal shape of the stent segments, the walls of the AVE stents consist of a large number of straight sections (struts) with curved sections (crowns) between each pair of straight sections. There is a sharp curve at the tip of each crown where the metal strand curves back to form another strut, as shown in the figure above that represents an AVE stent. AVE acknowledges that in the strut areas the thickness of the stent wall is measured by the cross-sectional diameter of the metal strands and that because the thin metal strands from which the stents are made are uniform in cross-section, the wall thickness of the AVE stents in the strut areas is uniform. In the crown area, however, AVE contends that the thickness of the stent wall should be measured not by the cross-sectional diameter of the thin metal strands that make up the stent wall, but by the length of the chords that cross the curved tip of the crown, as measured along a line drawn from the center of the stent

perpendicular to the wall. Because of the curvature of the crown tips, those chords become increasingly short as the point of measurement approaches the tip of the crown. Based on that proposed method of measurement, AVE contends that the thickness of the wall surface of its stents decreases to zero at the very tip of each crown and thus the wall thickness of each of its stents varies by 100 percent. The image below displays two measurements of thickness according to AVE's method of measurement. The left-hand box shows AVE's method of measuring the thickness of the stent wall in the strut area and at the crown. In the right-hand box, the first figure corresponds to the diameter of the stent as measured in the middle of the strut, while the second figure corresponds to the shorter chord across the crown of the stent, as measured at the tip of the crown.



AVE's argument about wall thickness is only a slightly modified version of its argument in the prior appeal. In that appeal, AVE argued that because the struts that make up the stent are round, the wall does not have uniform thickness. We rejected that argument because, "according to the patents' claims, it is the wall surface that needs to have a uniform thickness, and the full circumference of the round strut is not involved in making up the wall surface." Cordis I, 339 F.3d at 1362. We explained that experts from both sides agreed that "persons of ordinary skill in the art equate thickness with diameter in the case of round struts." Id. We thus rejected AVE's argument that

the thickness of the wall surface must be measured by each of the shorter chords that cut across the round or ellipto-rectangular cross-section of the strut, as depicted in the figures below.



AVE now argues that its stents do not meet the "substantially uniform thickness" limitation as a matter of law, because the thickness of the wall diminishes in the tapered end of the crown. That argument, however, like the argument we rejected in the last appeal, is based on the notion that a cylindrical metal strand produces a wall thickness that varies according to the length of the particular chord across the cylinder that is chosen for measurement. In the prior appeal, we rejected AVE's argument as applied to the struts, holding that "a stent with round struts can have a substantially uniform thickness as long as the round struts have substantially the same diameter." Cordis I, 339 F.3d at 1362. In this appeal, we reject AVE's argument as applied to the crowns, holding that a stent with round crowns can have substantially uniform thickness as long as the round crowns have substantially the same diameter.

AVE argues that a portion of our discussion of the wall thickness issue in the prior appeal requires a different result. In Cordis I, in an effort to illustrate the point that

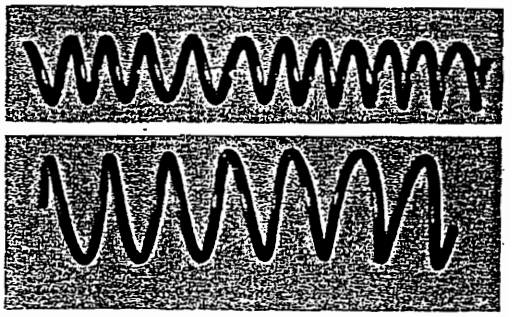
wall thickness is represented by the diameter of the struts, we characterized the diameter of the round strut as equal to the distance between the outer point of the strut that intersects an imaginary circle that constitutes the outer wall of the stent and the corresponding inner point that intersects a similar imaginary circle on the inside of the tubular member. 339 F.3d at 1362. Both at the 2005 trial and now on appeal, AVE has contended that our reference to "imaginary circles" justified, and indeed compelled, the court and the jury to conclude that the walls of its stents are not uniform in thickness. AVE's argument is predicated on the view that at the tip of each crown in the AVE stents, the inner imaginary circle would become larger and the outer imaginary circle would become smaller until the two met at the very tip of the crown, where the stent wall would have a thickness of zero.

Pursuant to its "imaginary circles" theory of wall thickness, AVE requested at the 2005 trial that the court instruct the jury that it should measure wall thickness using the following methodology:

> To determine whether the "substantially uniform thickness" limitation of all the asserted claims is satisfied, the thickness of the wall at each point along the stent is measured by looking at two imaginary circles, one on the outside, touching the outermost points of the circle, and one on the inside, touching the innermost points of the circle, and measuring the distance between these two circles. The thickness of the wall of the stent must be largely or approximately uniform along its length and between members. A wall that varies in thickness by as much as 100 percent is not largely or approximately uniform and thus does not have a substantially uniform thickness.

The district court rejected that requested instruction, and properly so. AVE sought to adopt the "imaginary circles" method of measuring thickness from our prior opinion in Cordis I, but without reference to the context in which that method was discussed. In Cordis I, we referred to the imaginary circles to illustrate the concept that

wall thickness, in the case of a wall made up of a thin metal strand having a round cross-section, should be measured by the diameter of the metal strand, not by some portion of the metal strand other than its diameter. AVE's use of imaginary circles would have exactly the opposite effect—it would result in the thickness of the stent wall being measured by reference to some portion of the metal strand other than its diameter. The trial court properly declined to give an instruction that would so clearly contravene the entire point of the analysis we employed in Cordis I.



Not only does AVE's interpretation of the phrase "substantially uniform thickness" conflict with our prior opinion in this case, but it conflicts with AVE's own explanation of the prior art. In its brief, AVE refers to two articles by Dr. Charles Dotter that discuss expandable stents consisting of cylindrical wire twisted into coils. AVE describes those stents, which are depicted here, as having "uniform wall thickness." That description is consistent with our conclusion in the prior appeal that "a stent formed from struts with circular or ellipto-rectangular cross-sections can have a wall of substantially uniform thickness." Cordis I, 339 F.3d at 1362. Yet there is no reason that the wall thickness of AVE's stents, which consist of sinusoidal curves disposed in a cylindrical plane, should be viewed any differently than the wall thickness of the stents disclosed by Dotter, which consist of coils disposed in a cylindrical plane. Put another way, the wall thickness in one of Dotter's stents would not cease to be uniform if the cylindrical wire making up the coil were bent into a sinusoidal shape from

place to place along the surface of the coil. For that reason as well, it was proper for the district court to decline to instruct the jury in accordance with AVE's request.

AVE also argues that it was error for the trial court to leave to the jury the issue of how to measure the thickness of the stent wall. According to AVE, the methodology of measurement should have been deemed an issue of law for the court rather than an issue of fact that was part of the infringement inquiry submitted to the jury. Even if the issue of the proper methodology for measurement should have been treated as a pure question of law, however, we reject AVE's argument that the trial court should have adopted AVE's methodology in determining how the wall thickness should be measured. Therefore, the trial court's treatment of the methodology issue as a question of fact could not have prejudiced AVE, as it gave AVE an opportunity to present its theory to the jury, even though the court would have been justified in refusing to permit AVE to introduce evidence regarding its theory as to how to measure wall thickness.

Although AVE took advantage of the opportunity it was given to present its evidence to the jury as to the proper method for measuring wall thickness, the jury ruled against AVE on that issue, and the jury's verdict was supported by substantial evidence. At trial, Cordis's engineering expert, Dr. Collins, testified that an engineer would "measure the thickness of the cross-section of the structural element" and that "the strut is the structural element." That is, even though the stent wall curves in the crown area, an engineer would nevertheless determine the thickness of the stent wall by measuring the thickness of the struts, which are uniformly thick. Dr. Collins stated that the rounding of the edges would not affect his analysis. AVE's expert, Dr. Wagoner, presented conflicting testimony, stating that an engineer would measure the thickness

of a stent's wall by comparing the inner diameter of the stent to the outer diameter. Under Dr. Wagoner's approach, the thickness measurement would taper near the ends of each of AVE's stents, leading to his conclusion that the stents do not have uniform thickness along two percent of their length. Dr. Collins's testimony, however, is not only consistent with the approach taken to the "wall thickness" issue in our prior opinion, but constitutes substantial evidence of infringement if the mode of measuring wall thickness is treated as part of the factual component of the infringement inquiry.

B

AVE next argues that it is entitled to JMOL of noninfringement of the '984 patent because its stents do not infringe the "flexibly connect" limitation of the asserted claims of that patent. In the 2000 trial, the jury found that AVE's stents infringed claims 1 and 3 of the '984 patent, which cover vascular grafts having a "plurality of thin-walled tubular members" with connector members "to flexibly connect adjacent tubular members." '984 patent, col. 11, ll. 53-55. Construing that limitation, the district court stated that "to flexibly connect adjacent tubular members means to connect in such a way as to allow turning, bowing or twisting without breaking. The connector member must provide flexibility, whether or not the adjacent tubular members themselves are flexible." In its motion for JMOL of noninfringement after the 2000 trial, AVE argued that its stents do not infringe because their connector members are not flexible. That issue was not part of the prior appeal, and after the 2005 trial, AVE raised it in a renewed motion for JMOL, which the district court denied.

As an initial matter, AVE reads the claim language and the district court's claim construction to require the connector members themselves to be flexible, rather than

simply providing flexibility to the device as a whole. As a result, in arguing that its stents do not meet the "flexibly connect" limitation, AVE relies on statements from Cordis's experts to the effect that the welds in and of themselves are not flexible. Neither the claim language nor the district court's claim construction, however, requires the connector members to be flexible. Rather, the claim language requires the connector members to "flexibly connect adjacent tubular members," and the district court construed that phrase to require the connector members to "provide flexibility." Even if the connector members themselves are not flexible, Cordis's evidence was sufficient to demonstrate that the connector members nevertheless provide flexibility to AVE's accused stents.

At the 2000 trial, one of Cordis's experts, Dr. Stringfellow, testified regarding a finite element analysis he performed to simulate bending in AVE's stents. Finite element analysis is a computer simulation technique used to model the real-world behavior of physical structures. Based on his simulation, Dr. Stringfellow estimated that the connectors, as used in AVE's GFX stent, account for about 22 percent of the stent's bending, while only making up five percent of the stent's length. AVE contends that Dr. Stringfellow's testimony should be disregarded. It argues that Dr. Stringfellow was not qualified to perform the finite element analysis because he had never designed a stent and was not familiar with the forces a stent would experience during delivery. AVE also argues that Dr. Stringfellow used incorrect assumptions and data in his simulation. The record, however, shows that Dr. Stringfellow had a doctoral degree in mechanical engineering and extensive experience performing finite element analyses. The trial court acted well within its discretion in holding that he was qualified to testify under

Federal Rule of Evidence 702. As for AVE's concerns about the assumptions and data that Dr. Stringfellow used in his analysis, AVE was free to, and did, present those concerns to the jury. Notwithstanding AVE's criticism of Dr. Stringfellow's methodology, the jury was entitled to credit Dr. Stringfellow's testimony, and based on that testimony it was reasonable for the jury to conclude that AVE's stents have connector members that satisfy the "flexibly connect" limitation, even if the connector members themselves are not flexible.

C

AVE contends that it is entitled to a new trial on several grounds. First, AVE challenges the district court's decision to prevent AVE and its experts from telling the jury that AVE's method of measuring stent wall thickness was endorsed by our opinion in the prior appeal in this case. As explained above, the portion of the opinion on which AVE relies dealt with whether "a stent formed from struts with circular or ellipto-rectangular cross-sections can have a wall of substantially uniform thickness." Cordis I, 339 F.3d at 1362. In explaining why we concluded that a jury could reasonably conclude that such a stent could have a wall of substantially uniform thickness, we described the use of "imaginary circles" as an illustration for how a jury could reach that conclusion. Contrary to AVE's contention, however, that portion of the opinion did not reflect this court's agreement with AVE's theory as to how to measure the thickness of the stent wall. Moreover, it was for the court, not the jury, to interpret this court's prior opinion. The district court therefore properly barred AVE and its experts from telling the jury that our prior opinion supported AVE's theory as to the proper manner to measure the thickness of the walls of AVE's stents.

AVE next argues that it was prejudiced by statements from Cordis's counsel criticizing AVE's method of measuring thickness. During closing argument, Cordis's counsel referred to AVE's method of measurement as "an utterly misleading analysis," "a big trick," and "intellectually dishonest," and argued that AVE was "misusing the concentric circles." AVE argues that those statements were prejudicially misleading because they gave the impression that AVE's method "was made up out of whole cloth and had no basis in law or fact." Those comments, however, were all made in the context of arguments for why Cordis's method provided a more rational approach to determining thickness, and its arguments were rooted in evidence on the record. Taken in context, Cordis's comments did not "run the risk of infecting the entire trial," and it is highly unlikely that they improperly influenced the jury. See Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1261 (Fed. Cir. 2004) (new trial not warranted where Chiron pointed to "no evidence of jury prejudice as a result of the identified statements, which were buried in a seventy-seven page transcript of Genentech's closing argument").

AVE next argues that it was prejudiced by statements from Cordis's counsel during closing argument regarding the method of measuring wall thickness. Counsel argued that AVE's method of measurement would not result in a 100 percent deviation in thickness because "you can't have a negative hundred percent deviation or variation." Counsel's point was that a 100 percent deviation in wall thickness in the crown area would be mathematically impossible because at the tip of the crown, where the level of variation in thickness would reach 100 percent, the stent ends, and therefore any measurement taken at that point or beyond could no longer be considered a

measurement of the thickness of the stent wall. The statement by Cordis's counsel was based on the following testimony by Dr. Wagoner during cross-examination:

> Q: [Y]ou will agree with me that as a mathematical matter there cannot be a hundred percent negative deviation?
> A: Deviation, a hundred percent deviation?
> Q: Yes.
> A: That's a different question. I agree with that.

While the comments of Cordis's counsel can be read to suggest that no reduction in thickness, no matter how great, could exceed the maximum 100 percent variation permitted by the "wall thickness" limitation as construed, counsel's statements taken in context appear principally directed to underscoring the disagreement between Cordis and AVE over the proper way to determine whether a stent meets the "substantially uniform thickness" limitation. It is highly unlikely that the argument made by Cordis's counsel had such a prejudicial effect as to deny AVE a fair trial.

AVE also objects to an argument in which Cordis's counsel told the jury that "you can't have a stent that goes up a hundred percent." AVE misunderstands the point Cordis's counsel was making. The context of the remark makes it clear that counsel was not saying it was impossible to have a stent with a 100 percent variation in thickness, but instead was saying that a stent could not have a wall surface that varied by more than 100 percent and still fall within the reach of the '762 patent. AVE is not entitled to a new trial as a result of those statements.

Next, AVE argues that it was prejudiced by the district court's exclusion of evidence demonstrating the clinical advantages of the tapered crowns on AVE's stents. AVE sought to have a medical expert testify that the tapered crowns provide for "improved treatment of calcified and tortuous lesions; improved trackability and

conformability; and improved side branch access." AVE's argument that it was prejudiced by the exclusion of that evidence is without merit. First, that evidence is irrelevant to the question of infringement. The jury was asked to determine whether AVE's stents infringe the '762 patent, not whether the stents perform better than the '762 patent's preferred embodiment. Second, despite the irrelevance of the clinical benefits of the tapered crown, AVE nevertheless was permitted to introduce such evidence from other sources. For instance, a senior engineer from AVE testified that the tapered crowns "minimize[] resistance in the vessel . . . and disruption of the vessel."

Finally, AVE challenges the court's instruction to the jury on obviousness, arguing that it conflicts with the Supreme Court's recent decision in KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007). AVE points to two sentences of the obviousness instruction as contrary to KSR. In those two sentences, the court told the jury, "If the prior art references as a whole do not teach, suggest or motivate that combination, then they may not be combined. The mere fact that the prior art can be modified does not make the modification obvious unless the prior art suggests the desirability of the modification." In the preceding sentence of the instruction, the court stated, "A suggestion to combine references may also flow from the nature of the problem or from the ordinary knowledge of those skilled in the art that certain references are of special importance."

AVE has not demonstrated that the jury instruction, when read in its entirety, conflicts with the Supreme Court's holding that the teaching-suggestion-motivation test should not be applied rigidly. Moreover, not only did AVE not object to the instruction

that it now challenges, AVE actually proposed that instruction. The instruction therefore either constitutes "invited error" that is not reviewable at all, or at most is subject to review under the "plain error" standard. See Maxwell Land Grant Co. v. Dawson, 151 U.S. 586, 606 (1894); Herman v. Hess Oil Virgin Islands Corp., 524 F.2d 767, 772 (3d Cir. 1975). Under Third Circuit law, to which we look for the standard to apply in reviewing claimed instructional errors from a district court in that circuit, AVE must show, at a minimum, that any error in the obviousness instruction was "fundamental and highly prejudicial" or that "the instructions are such that the jury [was] without adequate guidance on a fundamental question and our failure to consider the error would result in a miscarriage of justice." Bostic v. Smyrna Sch. Dist., 418 F.3d 355, 359 (3d Cir. 2005) (internal quotations omitted).

AVE argues that it should not be penalized for requesting an instruction based on the state of the law before KSR, because in its view KSR resulted in a significant change in the law. The Supreme Court, however, stated that "[t]here is no necessary inconsistency between the idea underlying the TSM test and the Graham [v. John Deere Co., 383 U.S. 1 (1966)] analysis." KSR, 127 S. Ct. at 1741. This court's error, the Supreme Court explained, was to "transform[] the general principle into a rigid rule that limit[ed] the obviousness inquiry." Id.; see also Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1357 (Fed. Cir. 2007) ("As long as the [TSM] test is not applied as a 'rigid and mandatory' formula, that test can provide 'helpful insight' to an obviousness inquiry." (quoting KSR, 127 S. Ct. at 1731)). In any event, even in the case of a change in the law, the Supreme Court has held that the plain error standard applies to a jury instruction to which no objection was made. See Johnson v. United

States, 520 U.S. 461, 465-66 (1997). Under that standard, AVE has not remotely demonstrated that it is entitled to a new trial on obviousness.

III

We turn next to BSC's appeal. Cordis asserts that a BSC stent called the NIR stent infringes claim 23 of the '762 patent. The NIR stent is manufactured from a stainless steel sheet. Slots are formed in the steel sheet by chemical etching. Unlike the stent disclosed in the '762 patent, the slots in the NIR stent are not rectangular. Instead, they are rounded at the ends, and each slot contains a U-shaped curve in the middle. The U-shaped portions protrude slightly when the stent is in its collapsed form. BSC refers to the U-shaped portions along the stent's surface as "U-loops." BSC's central argument is that those U-loops prevent the NIR stent from infringing claim 23.

At the 2000 trial the jury returned a verdict against BSC, finding that BSC infringed claim 23 under the doctrine of equivalents. The district court, however, granted BSC's motion for a new trial, holding that it should have instructed the jury regarding prosecution history estoppel for the "substantially uniform thickness" limitation. The district court stayed the new trial pending the outcome of Cordis's appeal in the AVE case, in which we found that "substantially uniform thickness" means that "the walls must be of largely or approximately uniform thickness" with variations of thickness of at least 100 percent disclaimed. Cordis I, 339 F.3d at 1360, 1362.

On remand, the district court amended its claim construction to be consistent with this court's construction in Cordis I, 339 F.3d at 1360-62, and Cordis Corp. v. Boston Scientific Corp., No. 04-1098, 99 Fed. App'x 928, 932-33 (Fed. Cir. May 28, 2004). The court construed the phrase "substantially uniform thickness" to mean that walls "must be of largely or approximately uniform thickness." The court then held a new trial, at the conclusion of which the jury once again returned a verdict of infringement. The district court denied BSC's ensuing motions for JMOL and a new trial.

BSC appeals from the verdicts in both the 2000 trial and the 2005 retrial. From the 2000 trial, BSC appeals the denial of its motions for JMOL and a new trial, arguing that the district court relied on an erroneous construction of the term "slots." In addition, BSC challenges the 2000 jury's verdict on the "wall surface" and "smooth surface" limitations. At the 2005 retrial, in which the issue of infringement was restricted to the "substantially uniform thickness" limitation, the jury returned a verdict of literal infringement. BSC appeals on several grounds from the denial of its post-verdict motions following that verdict. In addition, BSC appeals from the denial of a new trial on the issue of obviousness, which was litigated in the 2005 trial.

A

BSC first challenges the district court's construction of the term "slots" in the 2000 trial. Claim 23 covers stents with a wall surface having "a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member." '762 patent, col. 11, l. 67 through col. 12, l. 2. The district court construed "slots" to refer to both "complete" slots (slots that are bounded on all sides)

and "half" slots (slots that are not completely bounded). That construction allowed Cordis to press its theory that sections of the NIR stent falling between successive U-loops each meet the "tubular member" limitation because, viewed in that manner, the "tubular members" of the NIR stent would not have any complete slots. To support its argument that "slots" should be read to cover only complete slots, BSC relies on a passage from the specification that distinguishes half slots from complete slots:

> Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of tubular member 71 will only have a length equal to approximately one-half of the length of a complete slot 82, such half-slot 82 being bounded by members 78, 79, at both the first and second ends 72, 73 of tubular member 71.

'762 patent, col. 7, ll. 7-13. The initial reference to "alternating slots" refers to the half-slots at the end of the tubular member. Although the written description adopts a more specific term for those slots ("half-slots"), that does not foreclose the generic term "slots" from being used to refer to both half slots and complete slots. The written description uses the more specific phrase "complete slots" when distinguishing complete slots from half slots, and thus supports the inference that the term "slots," as used in claim 23, refers to both complete slots and half slots. If the patentee had intended claim 23 to only cover grafts with tubular members having complete slots, the patentee presumably would have drafted the claim to specify "complete slots," the term used in the written description to describe such fully bounded slots.

BSC also argues that the district court's construction of "slots" cannot be correct because, under that construction, the claim would cover inoperable embodiments. For that argument, BSC relies on Frank's Casing Crew & Rental Tools v. Weatherford International, Inc., 389 F.3d 1370, 1378 (Fed. Cir. 2004), in which this court construed a

means-plus-function limitation in a manner that avoided "render[ing] the patent internally inconsistent and the invention inoperable." Frank's Casing Crew does not provide the support for BSC's argument because means-plus-function claims by their very nature must be read to avoid rendering the invention inoperable. To be sure, even outside the means-plus-function context, we have stated that "a construction that renders the claimed invention inoperable should be viewed with extreme skepticism." Talbert Fuel Sys. Patents Co. v. Unocal Corp., 275 F.3d 1371, 1376 (Fed. Cir.), vacated and remanded on other grounds, 537 U.S. 802 (2002). But that statement refers to a construction that would render all embodiments of a claimed invention inoperable, not a construction that might cover some inoperable embodiments. See EMI Group N. Am., Inc. v. Cypress Semiconductor Corp., 268 F.3d 1342, 1349 (Fed. Cir. 2001) ("the party alleging inoperability must show that each disclosed embodiment in the patents was impossible or not enabled.").

In any event, the district court's construction of the term "graft" in claim 23 prevents the claim from covering inoperable stents. As BSC points out, the district court's construction of "graft" states that "[a] graft . . . must be functional, that is, once it is expanded and deformed it must be capable of serving to prevent a body passageway from collapsing." Therefore, a graft, or stent, would not infringe claim 23 if it consisted of only a single tubular member that would not be long enough to prevent a vessel from collapsing. Claim 23, however, recites a graft comprising a tubular member, not a graft consisting of a single tubular member. See Georgia-Pacific Corp. v. U.S. Gypsum Co., 195 F.3d 1322, 1327-28 (Fed. Cir. 1999) ("'comprising' is inclusive . . . or open-ended and does not exclude additional, unrecited elements or method steps," quoting Patent

and Trademark Office, Department of Commerce, Manual of Patent Examining Procedure, § 2111.03 (6th ed. 1997) ("MPEP")). Thus, the claim is not precluded from covering grafts that are constructed by linking multiple tubular members, any one of which, by itself, might not be capable of preventing vessel collapse.

BSC also contends that the district court's construction of the term "slots" is incorrect because a stent having only half slots could not satisfy the "tubular member" limitation, which the district court construed to mean "elongated" (i.e., "having a form notably long in comparison to its width"). BSC's argument, however, assumes that half slots must have a fixed size that would prevent a half-slotted tubular member from being elongated. The district court's construction of "slots" does not require BSC's assumption to be true. Whether the tubular members of the NIR stent, as identified by Cordis, meet the "tubular member" definition is a separate question of infringement that does not affect the correctness of the district court's construction of "slots." BSC has not challenged the jury's finding that the "tubular member" identified by Cordis is elongated.

B

BSC argues that the jury's verdict in the 2000 trial that the NIR stent infringes claim 23 must be overturned because no reasonable jury could find that the NIR stent literally infringes the "wall surface" and "smooth surface" limitations, and because prosecution history estoppel bars the availability of equivalents for those limitations. The trial court defined the "wall surface" limitation to require that the "outer surface of the tubular member must be disposed in a common cylindrical plane"; the court defined the "smooth surface" limitation to require that the "outside of the wall surface of the

unexpanded tubular member [have] a continuously even surface, without roughness, points, bumps or ridges, especially to the touch." The jury returned a general verdict of infringement under the doctrine of equivalents. Based on its analysis of the prosecution history, BSC argues that argument-based estoppel bars the availability of equivalents for both the "wall surface" and "smooth surface" limitations and that amendment-based estoppel bars the availability of equivalents for the "smooth surface" limitation.

1

As to the "wall surface" limitation, we hold that substantial evidence supports a finding of literal infringement and that the trial court therefore properly denied BSC's motion for JMOL on that issue. Because the district court correctly construed the term "slots," the jury was free to accept Cordis's theory that "tubular member" reads on the portion of the NIR stent lying between the stent's U-loops. Therefore, the U-loops do not prevent the tubular member from literally infringing the "wall surface" limitation. The only remaining question is whether, as BSC contends, the weld spots along the stent prevent the "wall surface" limitation from being literally infringed.

The weld spots to which BSC refers are formed as a result of the NIR stent's manufacturing process. After the stent's slot design is etched in a flat sheet of metal, the sheet is rolled into a tube and the ends of the sheet are welded together. That process forms a series of protruding weld spots along a seam of the stent. BSC argues that, with those weld spots, the NIR stent cannot meet the "wall surface" limitation, which the district court construed as requiring the outer surface of the tubular member to be "disposed in a common cylindrical plane." In pressing that argument, BSC reads the "wall surface" limitation narrowly to require the outer surface to define a perfect

cylinder. The district court's construction, however, does not require a perfect cylinder, which of course is an abstraction that cannot be achieved by any real-world device. Accordingly, even without applying the doctrine of equivalents, a jury could find that the outer surface of the NIR stent's tubular member infringes the wall surface limitation because the weld spots only insignificantly affect the shape of the wall surface. Each tubular section has only one weld spot, and Cordis introduced evidence that the weld spots do not rise significantly above the wall surface of the NIR stent and, taken together, make up only about one percent of the total area of the stent's metal outer surface. Thus, a jury could reasonably conclude that the presence of weld spots on the stent's surface does not sufficiently alter the cylindrical character of the outer surface to preclude a finding of literal infringement.

BSC argues in the alternative that it is entitled to a new trial on infringement because the district court should have ruled that prosecution history estoppel bars equivalents of the "wall surface" limitation. Even though we have held that substantial evidence supports a finding that the "wall surface" limitation was literally infringed, the jury returned a general verdict of infringement under the doctrine of equivalents. It is therefore possible that the jury found the "wall surface" limitation infringed under the doctrine of equivalents. If BSC's argument regarding prosecution history estoppel is correct, the jury's verdict would therefore be tainted. See Litton Sys., Inc. v. Honeywell Inc., 140 F.3d 1449, 1465 (Fed. Cir. 1998). For that reason, it is necessary to examine whether the court should have instructed the jury that equivalents were not available for the "wall surface" limitation, as BSC contends. After close review of the prosecution history, we reject BSC's argument and agree with the district court that prosecution

history estoppel does not bar application of the doctrine of equivalents with respect to the "wall surface" limitation.

On reexamination, Cordis responded to the examiner's rejection of the claims in the original '762 patent based on the Ersek sleeve. Addressing the claim term "wall surface," Cordis described Ersek as follows:

> The wall of the Ersek sleeve, to the extent that it exists, is comprised of twisted, inclined strands, which present inwardly and outwardly projecting edges and bridge portions that extend radially outwardly of the sleeve. This configuration does not provide "a surface" that is "disposed between the first and second ends" of a tubular member as is recited in claims 13 and 24.

Cordis then described the claimed invention as follows:

> As is evident from the specification of the '762 patent, with particular reference to Figure 1A, the connecting members and elongate members that collectively form the tubular member 71 have an outer surface that is disposed in a common cylindrical plane. No comparable wall surface is present in Ersek's fixation sleeve, and it would render Ersek inoperable for its intended purposes to modify sleeve 16 and eliminate the outwardly projecting edges, since the thus modified sleeve would eliminate the very structure contemplated by Ersek for retaining the associated graft or heart valve within the body passageway.

BSC argues that because the district court referred to the prosecution history to define "wall surface," it should have instructed the jury that prosecution history estoppel limits the range of equivalents available under the doctrine of equivalents. For that argument BSC relies on Omega Engineering, Inc. v. Raytek Corp., 334 F.3d 1314 (Fed. Cir. 2003), in which we described the relationship between prosecution disclaimer (limiting claim scope because of statements made by the patentee in prosecution) and argument-based prosecution history estoppel (limiting the scope of the doctrine of equivalents because of statements made by the patentee in prosecution). We explained that "for prosecution disclaimer to attach our precedent requires that alleged

disavowing actions or statements made during prosecution be both clear and unmistakable." Id. at 1325-26. We noted that the same standard applies to the doctrine of argument-based estoppel. Id. at 1326 n.1; see Cordis I, 339 F.3d at 1363. Relying on that statement, BSC argues that the district court should have held Cordis barred by argument-based estoppel from relying on the doctrine of equivalents with respect to the "wall surface" limitation because of Cordis's statements about that limitation in the prosecution history. The district court, however, correctly rejected that argument.

As BSC points out, an applicant can make a binding disavowal of claim scope in the course of prosecuting the patent, through arguments made to distinguish prior art references. Such argument-based disavowals will be found, however, only if they constitute clear and unmistakable surrenders of subject matter. Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1364 (Fed. Cir. 2006); Pharmacia & Upjohn Co. v. Mylan Pharms., Inc., 170 F.3d 1373, 1376 (Fed. Cir. 1999); Litton Sys., Inc., 140 F.3d at 1458. Moreover, the scope of such a disavowal will depend on the nature of the argument made by the patentee. As the court explained in Omega, 334 F.3d at 1324, even in the case of an unequivocal disavowal of claim scope, the court must construe the claim "congruent with the scope of the surrender." In order to constitute binding surrenders of claim scope, the statements in question must be such that "a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1457 (Fed. Cir. 1998) (en banc). If the court finds that the patentee made a clear disavowal of the subject matter that is subsequently asserted to be equivalent to the limitation in question, it will

preclude the patentee from asserting equivalency as to that subject matter. See Bayer AG v. Elan Pharm. Res. Corp., 212 F.3d 1241, 1252 (Fed. Cir. 2000).

In this case, as the district court found, Cordis made no such broad disclaimer of claim scope when it characterized the "wall surface" limitation in the course of the reexamination proceedings. Rather, Cordis simply made explicit the meaning of the term "wall surface" that was already implicit in the patent. When stating that the wall surface of the '762 graft was disposed in a common cylindrical plane, Cordis explained that that characterization was "evident from the specification," including Figure 1A (reproduced above), which shows the stent in its unexpanded state. The "common cylindrical plane" characterization of the wall surface was also consistent with the reference in the specification to the tubular member as having a "first predetermined, collapsed diameter d." '762 patent, col. 9, ll. 28-29. A tubular member with a predetermined diameter is a cylinder. The reference to the "common cylindrical plane" in the prosecution history therefore did not disclaim any subject matter that was otherwise within the scope of the claim language, but merely explained, in more explicit terms, what the claims already covered. In this regard, the prosecution history simply served the purpose of "inform[ing] the meaning of the claim language by demonstrating how the inventor understood the invention." Phillips v. AWH Corp., 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc). For that reason, there is no reason to treat Cordis's definitional explanation in the prosecution history as having the effect of surrendering all equivalents that would otherwise have been available under the patent. Because the district court did not find that Cordis's definition of the term "wall surface" constituted a clear and unmistakable disavowal of claim scope that would eliminate any equivalents

of the "wall surface" limitation, the district court properly declined to apply the doctrine of argument-based prosecution history estoppel to preclude all equivalents with regard to the "wall surface" limitation.

Cordis's only clear and unequivocal disclaimer as to the "wall surface" limitation was with respect to the wall structure of the Ersek sleeve, which Cordis made clear did not fall within the scope of its definition of "wall surface." In arguing that the Ersek sleeve does not satisfy the "wall surface" limitation, Cordis pointed to the relative thickness of the Ersek sleeve at the "bridge or bond areas" of the sleeve surface and "outwardly projecting edges" of the Ersek sleeve that are "the very structure contemplated by Ersek for retaining the associated graft or heart valve within the body passageway." For that reason, Cordis noted, the Ersek sleeve has "[n]o comparable wall surface" to one "disposed in a common cylindrical plane." That passage makes clear that Cordis disavowed only those devices, such as the Ersek sleeve, that have a wall surface not "comparable to" the wall surface of the disclosed stent. That statement clearly disavows a wall surface such as that in the Ersek sleeve, but it does not disavow any equivalents to the wall surface "disposed in a common cylindrical plane." See Conoco, Inc., 460 F.3d at 1364 (argument-based surrender of a particular possible equivalent is not "a clear surrender of other possible equivalents"); Uniroyal, Inc. v. Rudkin-Wiley Corp., 939 F.2d 1540, 1544 (Fed. Cir. 1991) (argument distinguishing a prior art device did not "curtail the scope of equivalents in such a manner as to preclude a finding that [the accused device infringes] under the doctrine of equivalents"). Thus, the prosecution history leaves room for the jury to determine whether the NIR stent has

a wall surface comparable to the stent disclosed in the '762 patent that would infringe either literally or under the doctrine of equivalents.

2

As to the "smooth surface" limitation, we hold that the district court properly sustained the verdict of infringement, although we do so on a different ground than that employed by the district court. Because we agree that the jury's verdict is well supported, we uphold the district court's rulings denying BSC's motions for JMOL and a new trial.

The district court held that the evidence at trial supported a finding of literal infringement of the "smooth surface" limitation because substantial evidence supported the jury's finding that the NIR stent had a smooth surface, i.e., what the court defined as a "continuously even surface, without roughness, points, bumps or ridges, especially to the touch." With respect to infringement under the doctrine of equivalents, the court concluded that the evidence would have supported a verdict in Cordis's favor on that theory as well. Moreover, the court held that amendment-based prosecution history estoppel did not apply, because Cordis managed to rebut the presumption of surrender that was created by the amendment to claim 23 on reexamination. See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002). On our view of the case, we find it unnecessary to decide whether the district court was correct to hold that Cordis successfully rebutted the Festo presumption with respect to the "smooth surface" limitation. That is because the definition of "smooth" that Cordis set forth in the prosecution history was sufficiently broad that it necessarily encompassed the NIR stent. Although the district court gave the jury a narrower definition at trial, Cordis has

argued on appeal that the instruction actually given by the district court was unnecessarily restrictive, and we agree. Under the correct instruction, a reasonable jury would necessarily have found that the NIR stent infringed the "smooth surface" limitation. As such, it is not necessary to look to the doctrine of equivalents as the basis for upholding the jury's verdict on that issue.

As discussed above, Cordis incorporated the "smooth surface" limitation from claim 23 into the independent claims of the '762 patent on reexamination in order to distinguish the Ersek device, which Cordis described as having a rough outer surface that prevented intraluminal delivery. In distinguishing the fixation sleeve disclosed in the Ersek patent, Cordis stated:

> The inner and outer surfaces of the Ersek sleeve 16 are not smooth, as that term is understood by persons of skill in the art (Andros Declaration, paragraphs 18 and 21. See also dictionary definitions of smooth—"having an even or level surface; having no roughness or projections that can be seen or felt", and rough—"not smooth or level; having bumps, projections, etc." (Exhibit 2 hereto) from which it is clear that such terms are commonly understood antonyms, and mutually exclusive of one another. Because the Ersek sleeve 16 does not have a smooth outer surface, it can not be intraluminally delivered, as that term is understood by persons of skill in the art (Andros Declaration, paragraphs 16 and 21).

The Andros declaration, which Cordis cited to the examiner, stated that the term "smooth," as used to refer to the outer wall surface of a stent of the type disclosed in the '762 patent, "is understood by those skilled in the art to mean that the wall surface is not rough and does not have outwardly projecting edges that would preclude intraluminal delivery and deployment of a low-profile graft from a remote location through a body passageway to the desired location." Moreover, Cordis called the examiner's attention to this court's decision in Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 450 (Fed. Cir. 1986), in which the court held that the term "smooth" should be

defined functionally, i.e., "that smooth means smooth enough to serve the inventor's purpose." The clear purpose of the invention in this case, Cordis noted, was "to provide a low-profile, small diameter product that is smooth enough that it can be intraluminally delivered from a remote location to a desired location without the risk of damaging the body passageway." Cordis further explained that, as indicated in the Andros declaration, the term "smooth" means "an absence of roughness that would make it inappropriate to deliver an Ersek-type device by catheterization." Finally, for "further examples of the meaning and common understanding of the term 'smooth surface'" Cordis referred the examiner to an article co-authored by the designer of the NIR stent in a publication entitled Handbook of Coronary Stents, which referred to the NIR stent as having a "smooth surface." See Kobi Richter, Yaron Almagor, and Martin Leon, The NIR Stent, Transforming Geometry, in Patrick W. Serruys & Michael J.B. Kutryk, Handbook of Coronary Stents 134 (2d ed. 1998).

That evidence from the prosecution history plainly indicates that the patentee intended for the term "smooth" to be defined functionally, so that a stent would be considered "smooth" if it was smooth enough to be capable of intraluminal delivery. While Cordis also referred to the term "smooth" as meaning not rough, i.e., not having "bumps, projections, etc.," Cordis made clear at several points in the prosecution history that the concept of roughness, as used in the context of vascular grafts, meant having an outer surface insufficiently smooth to enable intraluminal delivery.

BSC argues that to construe the term "smooth" in this fashion would render the "smooth surface" limitation superfluous, as another limitation of claim 23 requires that the vascular graft have "a first diameter which permits intraluminal delivery of the tubular

member into a body passageway having a lumen." In fact, however, a functional definition of smoothness would not render that limitation superfluous, because the "first diameter" limitation relates to the diameter of the graft in its compressed form (i.e., sufficiently small to permit intraluminal delivery), not to its smoothness.

Because there is no dispute that the NIR stent is capable of intraluminal delivery, and in light of the reference in the prosecution history characterizing the NIR stent itself as "smooth," we conclude that under the proper instruction, a reasonable jury would have had to conclude that the NIR stent literally infringed the "smooth surface" limitation. For that reason, we hold that the district court properly denied BSC's motion for JMOL with respect to the "smooth surface" limitation and that BSC was not prejudiced by the district court's finding that Cordis had rebutted the presumption that it had surrendered all equivalents for that limitation.

Although BSC has argued that we should not adopt the broader definition of "smooth surface" urged by Cordis, BSC contends that if we do accept that definition, it would be entitled to a new trial on the issue of obviousness in light of the broader scope of the asserted claim. BSC is correct, of course, that the definition of "smooth surface" that applies to the infringement analysis must also apply to the issue of obviousness. Whether, on the facts of this case, the broader definition requires any further proceeding with respect to the issue of obviousness, however, is not a matter that the parties have addressed in any detail on appeal and is best left for the district court to resolve on remand, particularly in light of the district court's intimate familiarity with the extensive and complex proceedings in this difficult case.

C

BSC next argues that the wall surface of its NIR stent does not exhibit "substantially uniform thickness," and that the district court erred in not granting judgment as a matter of law based on that issue.

The only infringement issue that was in dispute at the 2005 trial was whether the NIR stent literally infringes the "substantially uniform thickness" limitation. BSC and Cordis included statements in a joint pretrial stipulation that made clear the scope of the dispute that the parties agreed would be at issue in the 2005 trial:

> 8. For the purposes of this trial, it is admitted that the NIR stent as a whole meets the limitations in claim 23 of the '762 patent that require a "tubular member" having a "wall surface," either literally or under the doctrine of equivalents, but it is not admitted that a "C-region" of the NIR stent meets the "tubular member" limitation.
>
> 9. For the purposes of this trial, it is admitted that the NIR stent meets each limitation of claim 23 of the '762 patent, either literally or under the doctrine of equivalents, except for the "substantially uniform thickness" limitation.

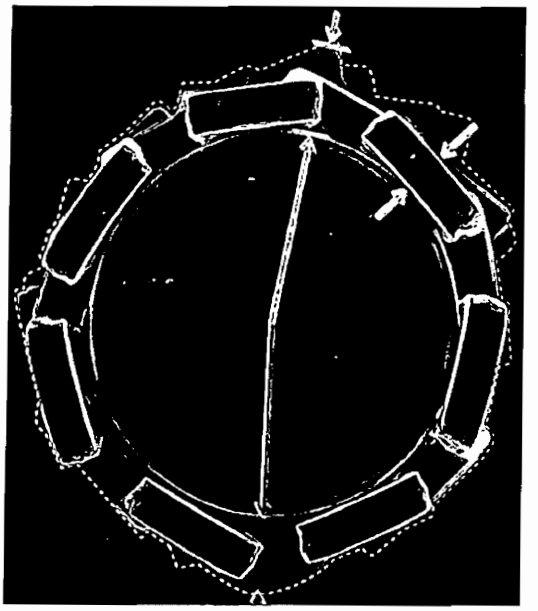
The district court issued the following construction of "substantially uniform thickness" to reflect our decision in Cordis I: "The wall of a tubular member must be of largely or approximately uniform thickness." BSC did not challenge that claim construction. Applying that construction to the NIR stent, the jury returned a verdict of literal infringement of that limitation.

On appeal, BSC argues that Cordis did not present any evidence that the NIR stent has a uniformly thick wall, and that instead Cordis only presented evidence that the struts of the NIR stent have uniform thickness. In essence, BSC challenges Cordis's approach to measuring the thickness of the stent wall. It argues that the correct approach to measuring the thickness of the NIR stent's wall requires measuring

from each point on the stent's outer surface to a corresponding point on an unvarying cylindrical plane generally defined by the inner boundary of the stent wall. When thickness is measured according to that method, BSC argues, the protruding U-loops and the weld spots produce variations in the thickness of the stent's wall that fall outside the literal scope of the "substantially uniform thickness" limitation.

We reject BSC's argument. The district court's claim construction, to which BSC did not object, did not specify how a person of ordinary skill in the art would determine wall thickness. That was left for the jury to decide as a question of fact, and the jury was entitled to rely on expert testimony that measuring the metal struts provides the correct measurement of wall thickness. Dr. Buller, an interventional cardiologist who testified for Cordis, stated that he understood the stent walls to be the "metal of the stent." Another of Cordis's experts, Dr. Richter, testified that he "would agree that the metal is what defines the wall." Even one of BSC's experts, Dr. Snyder, stated, "As a cardiologist, I would take [the thickness of the wall of a stent] to mean the thickness of the metal from which it was constructed." From that evidence, the jury could reasonably conclude that the thickness of the metal struts was the proper measure of the thickness of the stent wall. That is particularly true in light of the inconsistency in the way the outer and inner portions of the stent wall are treated under BSC's method of measuring wall thickness. BSC's approach takes account of the U-loops when determining the outer surface, but not when determining the inner surface, which accounts for the asserted variation in the thickness of the stent wall. The figure below shows measurements of wall thickness according to BSC's approach. The outer surfaces of

the U-loops are outlined by the dotted line, and the empty space underneath the U-loops is included in BSC's measurement of wall thickness.



BSC argues that during reexamination Cordis disclaimed equating the thickness of the stent wall with the thickness of the metal struts. In addressing the wall thickness limitation, the examiner characterized the fixation sleeve of the Ersek patent as having a uniform wall thickness because the elongate members of the sleeve, "although twisted, have the same thickness as the remainder of the sleeve." The examiner explained that the sleeve was formed from a sheet of metal having uniform thickness "and the twisting of the members . . . does not change their thickness." Cordis responded by arguing that the wall of the Ersek sleeve is of varying thickness "because the strands of the sleeve have twisted out of the plane of the starting material." Noting that the bridges at the junctions of the strands in the Ersek sleeve protrude inwardly and outwardly of the plane of the starting material, Cordis argued that the Ersek sleeve "has a non-uniform wall of varying thickness." As Cordis further explained, the "bridge portions" of the Ersek sleeve "are several times as thick as the strands." Figure 5 of the Ersek patent, shown

below, displays the bridge portions (22) having thickness twice as great as the strands in between.

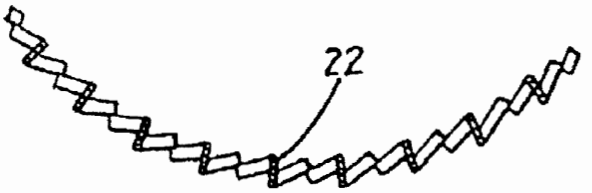


FIG. 5

Cordis's statements during reexamination do not constitute a clear and unequivocal disclaimer of claim scope, as BSC contends. Read in context, those comments are best understood to mean that the intentional deformation of the metal strands in the Ersek sleeve results in certain portions of the wall of the sleeve being much thicker than other portions, as measured from a point along the center line of the sleeve, i.e., the sleeve's longitudinal axis. The comments do not, as BSC argues, require that the measurement of thickness include not only the metal of the U-loops but also the space underneath the U-loops. Instead, they reflect the view that the thickness of the stent wall is a function of the thickness of the metal segments making up the wall. That was the point of the observation that the portions of the Ersek sleeve designated as "bridges" have double thickness when measured from the center line of the stent, even though they are part of the same sheet of metal as the portions designated as "strands." In that respect, the prosecution history does not support BSC's proposed method of measuring wall thickness, which includes counting the space underneath the U-loops as part of the wall. Nor does it support BSC's contention that Cordis clearly

and unambiguously disavowed its theory that the thickness of the metal struts should determine the thickness of the stent wall surface.

BSC further contends that it was prejudiced by the district court's answer to a question from the jury regarding the construction of "wall surface" and that it is entitled to a new trial on that ground. During deliberations, the jury asked the trial judge to "clarify further the words 'disposed' and 'common cylindrical plane' in the definition of wall surface." After a telephonic conference with the parties, the judge gave the jury the following instruction:

> The claim language in the case was previously determined. I cannot define them further.
>
> Let me remind you that the "wall surface" limitation is not in dispute in this case. The only limitation in dispute in this case is the "substantially uniform thickness" limitation.

BSC argues that the court's instruction was prejudicial because it suggested to the jury that the "wall surface" limitation was literally infringed and it implied that the NIR stent's wall surface is disposed in a common cylindrical plane. The instruction, however, said nothing about whether the "wall surface" limitation had been met literally or by equivalents. Moreover, during the telephonic conference, the judge asked BSC's counsel if it was correct to say that the "wall surface" limitation was not in dispute, and BSC's counsel confirmed that it was. That response was consistent with the pretrial stipulation in which Cordis and BSC agreed that for the purposes of the 2005 trial the "wall surface" limitation was to be considered met literally or under the doctrine of equivalents. In light of the limits the parties had agreed to place on the issues presented to the jury for purposes of the infringement inquiry, the court's handling of the jury's question was entirely appropriate.

D

Finally, BSC challenges two of the court's evidentiary rulings that bore on the issue of obviousness. At the 2005 trial, Cordis introduced evidence pertaining to the intraluminal delivery of stents on angioplasty balloons in an effort to distinguish the structure of claim 23 from the structure disclosed in the Ersek patent, which is incapable of intraluminal delivery. Because claim 23 is an apparatus claim rather than a method claim, BSC sought to introduce evidence regarding several of the '762 patent's unasserted method claims that include an intraluminal delivery step and other patent claims involving flexible stents. BSC argues that it needed to introduce that evidence to point out the differences between those other claims and claim 23 of the '762 patent so as to focus the jury on the obviousness of claim 23 and to counter Cordis's evidence as to the general success of the balloon expandable coronary stent. The district court, however, excluded the proffered evidence under Federal Rule of Evidence 403, which authorizes trial courts to exclude evidence when its probative value is substantially outweighed by factors such as delay, the danger of unfair prejudice, or the risk of introducing confusion or misleading the jury. Because the evidence BSC sought to introduce did not focus on claim 23, the only asserted claim in the 2005 trial, it was within the district court's discretion to exclude that evidence out of concern that it would confuse the jury. We are not persuaded that the evidence of other patents and claims was needed in order to give the jury an adequate basis for assessing the question of the obviousness of the invention recited in claim 23.

BSC also sought to introduce evidence about Cordis's interest in acquiring the rights to the NIR stent from BSC. Cordis had introduced evidence of commercial

success, and BSC sought to rebut any connection between claim 23 and the commercial success of Cordis's stents by demonstrating that Cordis's commercial success was due mainly to its stent's flexibility, a feature not covered by claim 23. BSC argued that it should have been permitted to introduce evidence of Cordis's plans to purchase the rights to the NIR stent because of the NIR stent's superior flexibility. The district court excluded that evidence under Rule 403 based on the court's conclusion that the commercial success of the NIR stents had limited probative value in determining the obviousness of claim 23. That evidence was relevant in the 2000 trial, because in that trial the doctrine of equivalents was asserted, and the NIR stent's greater flexibility related to BSC's argument against a finding of equivalency. But with respect to the issue of obviousness, the district court properly focused the jury's attention on the prior art and the claimed invention instead of the accused device. It was not an abuse of discretion for the court to exclude the evidence proffered by BSC regarding the properties of the accused device.

IV

In its cross appeal, Cordis challenges the district court's invalidation of claim 44 of the '762 patent under 35 U.S.C. § 305. Section 305 permits the owner of a patent that is in reexamination "to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301 of this title, or in response to a decision adverse to the patentability of a claim of a patent." As a limitation on a patent owner's ability to add or amend claims, section 305 provides that "[n]o proposed amended or new claim

enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding."

Cordis added claims 44 through 59 to the '762 patent during reexamination in an amendment responding to an office action that was mailed on June 1, 1998. That office action rejected all but two of the claims of the '762 patent as obvious or anticipated in light of various prior art references. In the July 21, 1998, amendment filed in response to that office action, Cordis made a number of changes, including canceling some claims, modifying others, and adding claims 44 through 59. All of those changes were stated to be "[r]esponsive to the Office Action mailed June 1, 1998." Cordis stated in the response that "claims 44-59 are all narrower in scope than the original claims, and provide specific protection for aspects of the disclosed invention which have been incorporated into competitive products and methods."

At trial, the district court submitted the issue of invalidity under section 305 to the jury but reserved decision on whether that issue was ultimately a question for the court. After the jury returned a verdict holding the claims invalid, the district court determined that invalidity under section 305 should be decided by the court rather than the jury. Using the jury verdict as an "advisory opinion," the court nevertheless found claim 44 invalid because, in its view, claim 44 was not added "(1) to distinguish the invention as claimed from the prior art" or "(2) in response to a decision adverse to the patentability of a claim of a patent" as required by section 305. To the contrary, the court concluded that claim 44 was "added solely to cover competitors' stents, and not for a permissible reason under § 305."

In holding claim 44 invalid, the district court incorrectly interpreted section 305. The portion of section 305 on which the district court relied permits a patentee to add claims (1) that distinguish the invention from the prior art cited under section 301 and (2) that are added in response to an office action adverse to the patentability of a claim. Claims added under either clause must satisfy section 305's substantive limitation, which prevents patent owners from adding new claims that enlarge the scope of the patent's coverage.

Cordis specifically stated that the changes it made in its July 21, 1998, submission to the PTO, including the addition of claims 44 through 59, were "[r]esponsive to" the office action that had rejected all but two of the claims of the '762 patent in light of prior art references. Moreover, Cordis was free to include the new claims even apart from the office action if they were added to distinguish the invention from prior art cited under section 301. Section 305 does not require the patent owner to include an express statement that the new claims distinguish the prior art or remarks indicating how the new claims distinguish the prior art references. If the claims fail to distinguish the prior art, the claims will be rejected on the appropriate grounds; for that reason, it may frequently be in the patent owner's interest to include such remarks, but they are not necessary to satisfy section 305. For purposes of assessing validity under section 305, the MPEP directs the examiner to determine only whether any added claims impermissibly "enlarge the scope of the original claims." 37 C.F.R. § 1.552(b). Here, the district court acknowledged, and BSC concedes, that claim 44 does not broaden the scope of coverage of the '762 patent.

Because we reverse the judgment with respect to claim 44, we address an issue that BSC raised in a letter submitted on October 1, 2007, after the briefs in this case were filed. In the letter, BSC asked this court to review the judgment of infringement of claim 44 based on the decision of this court in BMC Resources, Inc. v. Paymentech, L.P., 498 F.3d 1373 (Fed. Cir. 2007), which was decided after all the briefs were filed in this case, but before oral argument. BSC's effort to raise a new argument with respect to that issue comes too late. Although BSC challenged the judgment of infringement of claim 44 based on the district court's construction of "slots," which we affirm, BSC did not challenge any findings relating to its connection to or control over the infringing activity. Therefore, BSC has waived review of that issue. See Engel Indus., Inc. v. Lockformer Co., 166 F.3d 1379, 1383 (Fed. Cir. 1999).

V

Cordis has asked this court to direct the district court to reinstate the damages verdicts from the 2000 trial. We decline to do so because there may be other issues that need to be addressed before a final judgment can be entered in these cases. For example, we have noted that the district court may have to revisit the issue of obviousness raised by BSC at the 2005 trial in light of the revised claim construction we have adopted for the term "smooth surface." For another, we note that the district court stated at one point that a new trial on damages may be required to determine whether other stents can be considered noninfringing alternatives under the construction of "substantially uniform thickness" from AVE's prior appeal. There may be other matters that we are not aware of that the district court needs to address before it can bring these long-running cases to final judgment. In light of the protracted and complex

proceedings in the district court, the district judge is in a far better position than we are to determine what remains to be done to bring these matters to a close.

AFFIRMED IN PART, REVERSED IN PART, and REMANDED.